



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

June 29, 1987

[Handwritten signature]

Isaac Jarkovsky, Esq.
Assistant General Counsel - Patents
Bristol-Meyers Company
345 Park Avenue
New York, New York 10154

RE: Patent Term Extension
Application for
U. S. Patent 4,182,763
Issued January 8, 1980

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,182,763, issued January 8, 1980, is eligible for patent term extension under 35 USC 156. The period of extension has been determined to be 2 years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register on December 19, 1986, as follows:

$$\begin{aligned}\text{Period} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1073) + 1385 \\ &= 1922 \text{ days}\end{aligned}$$

Since the regulatory review period began April 16, 1972 before the patent issued January 8, 1980, only that portion of the regulatory review period occurring after the date the patent issued has been considered in the determination of the length of the maximum extension. 35 USC 156(c). (From April 16, 1972 to January 8, 1980, is 2823 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: 3896 - 2823 = 1073 days. No determination of a lack of due diligence was made. 35 USC 156(c)(1). The exception of 35 USC 156(c)(3) does not operate to reduce the maximum period of extension determined above. However, the limitation of 35 USC (g)(4)(C) applies in the present situation because Patent No. 4,182,763 was issued January 8, 1980 before the date of enactment (September 24, 1984) of 35 USC 156; the date of exemption under Section 505(i) of the Federal Food, Drug and Cosmetic Act involving Buspar became effective April 16, 1972 was before the date of enactment, and the product was not approved for commercial marketing or use September 29, 1986 before the date of enactment. Since the period of extension calculated under 35 USC 156(c) for Patent No. 4,182,763 and Buspar cannot exceed two (2) years under 35 USC 156(g)(4)(C), the period of extension will be for two (2) years.

A single request for reconsideration of this final determination as to eligibility and the length of extension of the term of U.S. Patent 4,182,763 may be made if filed within one (1) month of the date of this notice. In the absence of such request, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,182,763, a certificate of extension, under seal, for a period of 2 years. The rights derived from the Patent during the period during which the patent is extended are defined in 35 USC 156(b).

C.E. Van Horn

Charles E. Van Horn, Director
Patent Examining Group 120

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs
Food & Drug Administration
5600 Fishers lane
Rockville, MD 20857

Re: BUSPAR
FDA Docket No. 86E-0456